



DEPARTMENT OF HEALTH & HUMAN SERVICES

**Public Health Service
Food and Drug Administration**

93693d

San Francisco District
1431 Harbor Bay Parkway
Alameda, CA 94502-7070
Telephone: 510/337-6700

VIA FEDERAL EXPRESS

Our Reference: 2954543

November 14, 2002

Edward S. Sempliner, President
Jeremiah's Fine Foods, Inc.
21 East Pier
Sausalito, California 94965

WARNING LETTER

Dear Mr. Sempliner:

On February 6, 8, 11, and 14, 2002, we inspected your seafood processing facility located at 41 Hamilton Drive, Unit G, Novato, California. We found that you have serious deviations from the Seafood HACCP regulations in Title 21, Code of Federal Regulations, Part 123 (21 CFR 123). In accordance with 21 CFR 123.6(g), failure of a processor to have and implement a HACCP plan that complies with this section, or otherwise operates in accordance with the requirements of this part, renders the fishery products adulterated within the meaning of Section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the Act). Accordingly, your Seafood Cakes and Seafood Burgers are adulterated, in that the products have been prepared, packed, or held under insanitary conditions whereby they may have been rendered injurious to health. You may find the Act and the seafood HACCP regulations through links in FDA's homepage at www.fda.gov. See attached handout on how you can obtain a copy of the Fish & Fisheries Products Hazards & Controls Guidance, 3rd edition, June 2001. We listed the deviations on a Form FDA 483 and discussed them with you at the conclusion of the inspection. Your serious HACCP deviations were as follows:

1. You must conduct a hazard analysis to determine whether there are food safety hazards that are reasonably likely to occur and you must have a written HACCP plan to control any food safety hazards that are reasonably likely to occur, to comply with 21 CFR 123.6(a) and (b). However, your firm does not have a HACCP plan for:

- a) Paella Cake with Shrimp to control the food safety hazards of pathogen growth and toxin formation and undeclared sulfite inclusion.
 - b) Risotto Cake Salmon & Corn and Pasta Cake Tuna Noodle to control the food safety hazards of pathogen growth and toxin formation.
2. You must conduct a hazard analysis to determine whether there are food safety hazards that are reasonably likely to occur and have a HACCP plan that, at a minimum, lists the food safety hazards that are reasonably likely to occur, to comply with 21 CFR 123.6(a) and (c)(1). A food safety hazard is defined in 21 CFR Part 123.3(f) as “any biological, chemical, or physical property that may cause a food to be unsafe for human consumption.”

Your firm's HACCP plan for Seafood Cakes also does not list the food safety hazard of the presence of undeclared sulfites in products that include shrimp. Typically, processors establish critical control points at packaging, receiving, or finished product labeling. Information on sulfites may be found in the Fish and Fisheries Products and Hazards Guidance: Third Edition, Chapter 19.

3. You must conduct a hazard analysis to determine whether there are food safety hazards that are reasonably likely to occur and have a HACCP plan, that, at a minimum, lists the critical control points, to comply with 21 CFR 123.6(a) and (c)(2). A critical control point is defined in 21 CFR Part 123.3(b) as a “point, step, or procedure in a food process at which control can be applied and a food safety hazard can as a result be prevented, eliminated, or reduced to acceptable levels.” However, your firm's HACCP plan for Salmon Mushroom Risotto does not list the critical control point of “Cooling of the Cooked Rice” for controlling the food safety hazard of pathogen growth and toxin formation, specifically Bacillus cereus, as a result of time/temperature abuse.
4. You must have a HACCP plan that, at a minimum, lists the critical limits that must be met, to comply with 21 CFR 123.6(c)(3). A critical limit is defined in 21 CFR Part 123.3(c) as “the maximum or minimum value to which a physical, biological, or chemical parameter must be controlled at a critical control point to prevent, eliminate, or reduce to

an acceptable level the occurrence of the identified food safety hazard.” However, your firm’s HACCP plans for Seafood Cakes, Seafood Sausages, and Salmon Mushroom Risotto

- list a critical limit at the Cooking (Baking or Poaching) critical control point (CCP) that is not adequate to control pathogen survival through cooking.

Due to temperature variations from one piece of cooking seafood to the next, FDA does not consider internal temperature monitoring to be an effective safety measure. FDA currently recommends that cook temperatures be monitored continuously, such as a temperature data logger, or when boiling, by visually observing the boiling of water.

- do not list a critical limit at the Cooking (Baking or Poaching) critical control points. In addition to temperature, you must monitor the length of your cook cycle.

A scientific study of your cook cycles and equipment can help you best determine what limits should be implemented to ensure the overall safety of your products.

In addition, our investigator observed that your firm has not consistently implemented the monitoring procedures you have listed in your plans or recorded observations regarding those procedures. The implementation of your listed procedures and the maintenance of records of your observations is part of the requirements listed in 21 CFR 123, specifically Section 21 CFR 123.6(b).

5. You must maintain sanitation control records at the processing facility for at least two years after the date they were prepared in the case of frozen products and one year in the case of refrigerated products to comply with 21 CFR 123.11(c). However, your firm’s sanitation control records for your frozen products were only maintained for a year.
6. You must adequately monitor sanitation conditions and practices during processing, to comply with 21 CFR 123.11(b). However, your firm did not monitor employee practices with sufficient frequency to ensure control as evidenced by the presence of employees without hairnets in the processing area and an employee wearing a ring while manipulating food.

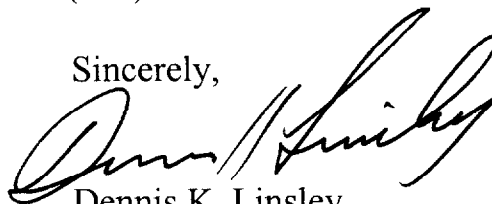
We may take further regulatory action if you do not promptly correct these violations. For instance, we may take action to seize your products and/or enjoin your firm from operating.

Please respond in writing within fifteen (15) working days of receipt of this letter. Your response should outline the specific things you are doing to correct these violations. We acknowledge the receipt of your response to the latest FDA 483; however, your response did not adequately address our concerns because you did not include documentation of your corrections. We recommend that you include in your response documentation such as time/temperature monitoring records, sanitation records, revised HACCP plans, etc. If you cannot complete all of the corrections before you respond, we expect that you will explain the reason for your delay and state when you will correct any remaining deficiencies.

This letter may not list all of the deviations at your facility. You are responsible for ensuring that your processing plant operates in compliance with the Act, the Seafood HACCP regulations, and the Good Manufacturing Practice regulations. You also have a responsibility to use procedures to prevent further violations of the Federal Food, Drug, and Cosmetic Act and all applicable regulations.

Please send your reply to the Food and Drug Administration, Attention: Erlinda N. Figueroa, Compliance Officer, 1431 Harbor Bay Parkway, Alameda, California 94502-7070. If you have questions regarding any issue in this letter, please contact Ms. Figueroa at (510) 337-6795.

Sincerely,

A handwritten signature in black ink, appearing to read "Dennis K. Linsley", written in a cursive style.

Dennis K. Linsley
District Director
San Francisco District

Attachment